

DAIDS	Appendix 2	No.: DWD-POL-SM.0200A2
-------	------------	------------------------

Sample Clinical Quality Management Chart Review Tool

(SAMPLE ONLY. The template below is provided for your convenience as an example of how this information may be provided. You may modify this as appropriate.)

Participant Identification # _____ Reviewed from (Visit #) _____ Through (Visit #) _____

Name of Reviewer _____ Date of Review _____

<i>Indicator</i>	<i>Criteria</i>	YES	NO	N/A
1. Consent	Current, IRB/EC approved version of consent signed?			
	Participant signed and dated (in ink) consent, prior to study-specific procedures?			
2. Participant Education	Education provided per protocol?			
3. Test of Understanding	Provided per protocol and documented. (If applicable)			
4. Eligibility	All eligibility criteria met and documented?			
5. HIV Prevention Counseling	Counseling provided per protocol, and documented?			
6. Lab Tests and Procedures	All required tests/ procedures performed and documented?			
	Any missed tests documented, with reason provided?			
7. Concomitant Meds	Source documentation and CRF consistent?			
	Is participant taking any prohibited meds?			
8. Study Product Administration	Study product administered per protocol and documented? (If applicable)			
	Reactogenicity recorded at appropriate timeframes with appropriate follow-up? (If applicable)			
9. AE/SAE/EAE Reporting	Adverse events recorded and reported properly?			
	Are there any missed (unreported) AEs?			
	Are there any missed (unreported) SAEs?			
	Are there any missed (unreported) EAEs?			
10. Endpoints	Has the participant reached any protocol-defined endpoints?			
	If yes, are they documented properly and protocol			

